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09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/716,146	BOYLE, CHRISTOPHER T.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,20,26-28 and 30-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,20,26-28 and 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 16, 20, 26-28, and 30-37 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Brown (US 6,071,305) is inappropriately used in a rejection since the Board decided that "Brown does not describe a stent with a metal base layer and a second layer also made of metal". In the rejection over Brown that was sent to the Board, second layer was considered by the examiner to be 34, 44, and 49 which are polymeric membranes or osmotic non-metal layers. The examiner had interpreted the claim such that the second layer did not require metal. The board however reversed this rejection based on the decision that the second layer indeed need be fabricated of metal (as is the first layer, see pg.12-12 of decision mailed April 30, 2008). Since layers 34, 44, and 49 are not metal, the rejection was reversed. It was the specific rejection of Brown that was reversed by the Board though, not the reference as a whole. Under a new and different interpretation of the Brown reference (see more details below), layer may be considered a portion/thickness/layer of the stent strut (12), which under this interpretation, the first and second layers *are* made of metal.

The applicant has also agued that Whicher does not teach a plurality of vacuum deposited structural elements including a complex finished geometry. The examiner disagrees. Both Brown and Whicher disclose stents of complex geometry. See Brown col.7, lines 34-39, each "structural element" being a strut (12) and the complex geometry being the "expandable tube stents, roving wire stents, and wire mesh stents". Whicher also discloses complex geometries that are vacuum deposited (tailor geometries, col.3, lines 15-25; col.6, lines 21-57; fig.2, 3).

The applicant has also argued that Whicher does not disclose (regarding claim 30) controlled heterogeneities thereupon. The examiner disagrees. Whicher clearly discloses controlling properties of the material and its microstructure (heterogeneities) by the deposition process (col.2, lines 6-10, 16-31; col.3, lines 17-25). See also Board decision for related application 09/707,685 mailed on September 30, 2008 (common inventor, same assignee and same attorney of record) in which the Whicher reference was affirmed based on similar claim language. Whicher's method inherently control's the stents heterogeneities, because Whicher discloses the same vacuum deposition processes (sputtering, ion beam deposition) and use of the same materials used by the applicant. Applicants disclose in their specification that it is the vacuum deposition process that controls the heterogeneities. Since Whicher is using the same process as the applicant, Whicher is inherently "controlling heterogeneities" just as much as the applicant is.

Board Decision

The board decision mailed April 30, 2008 reversed the rejection of Brown (US 6,071,305), agreeing with the applicant that the claims require *both* the base layer and second layer of the structural elements to be made of metal, thus reversing the rejection of Brown since the examiner had interpreted the structural elements to only *comprise* metal, and not necessarily both layer requiring the metal (the examiner had interpreted membrane and osmotic material to constitute a “layer”, however these “layers” were not metal; in figures 5, 7, 8, and 10 of Brown shown in attachments to examiners answer). The board reversed Brown due to the interpreted “layers” of the examiner were not each metal, as required by the claim. This is relevant since

Brown has been applied herein *under a different interpretation* in which a different embodiment contains both a base and second layer each being metal, see below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20, 26-28, and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 6,071,305, cited previously) in view of Whicher et al. (US 6,938,668 B2, cited previously). Brown discloses an endoluminal stent for delivering a bioactive agent (col.1, lines 12-20) comprising a plurality of structural elements (12; only one structural elements is shown in fig.1, 2 however a plurality of structural elements 12 are disclosed as additional possible embodiments at col.7, lines 34-39; mesh stent, each filament of the plurality of filaments in the mesh being a member 12), the structural elements (12) forming a complex geometry (other configurations such as coiling stents, expandable tube stents, roving wire stents, and wire mesh stents, col.7, lines 34-40) each structural element (12) having a wall thickness (cross sectional thickness of an element 12 seen in figs.3-10) and fabricated of metal (col.7, lines 11-18) comprising a base layer (considered luminal surface or layer 18) and a second layer (considered abluminal surface or layer 19) covering the base layer (see figures 2A, 3, 6, 8 and attachments 2-5 which more clearly show location of "layers"), a void space (20) intermediate the layers and enclosed therebetween, a plurality of pores (22, 28, 54) passing through the second

layer (19), such that the void space is only open through the pores (see figs.3, 6 for example), and at least one bioactive agent (23; col.5, lines 1-27).

*with respect to the term “layer”: applicant's only recitation of the word layer is referral to a deposition process, in which layer upon layer is deposited until forming one unitary device (seen in applicant’s figures). The claims refer to a stent which is shown in applicants figures 2-7, which contains structural elements 21 or 31 shown generally cylindrical, having a longitudinal axis (shown in figure 7) and a round cross-section (shown in fig.3 and 6-figure 6 shown two adjacent structural elements). The “layers" are not clearly pointed out in the figures as the specification only refers to "layers” as depositing layer upon layer to form the device shown in the figures. It is not clear where one layer starts and ends, but it would appear applicant is referring to an abluminal and luminal "layer” (referenced as 26, 28, 33, 35). Brown has shown the same type of structural elements 12, having a generally round cross-section (figs.3-10; which also may be alternately be other cross-section such as square, col.6, lines 1-5 which would form flat planar layers) with an inner void space 20. Structurally, the elements of Brown are the same as the applicants (compare fig.2a of Brown to fig.7 of applicant; compare fig.3, 6, 8 of Brown to applicants fig.6 of applicants, keeping in mind that applicants fig.6 shows two side by side structural elements; see attachments 1-5 provided in previous action). The structural elements are the same. Therefore, a "layer" of applicant’s structural element may also be considered a "layer" of Brown's structural element. See attachments, wherein the second layer is shown shaded to distinguish it from the base layer, both layers being part of structural element 12 which is fully made of metal, both layers are metal.

Brown discloses an endoluminal stent substantially as claimed (see above), however does not disclose vacuum deposition metal to form the structural elements (method of manufacture). Brown is silent to mention any method of manufacture for stent 11 (only method disclosed is for embodiment in fig.17-a different embodiment-a method shown in figs.13-18; col.11, lines 62-67; which is disclosed as cutting by laser or other conventional cutting means). Whicher teaches in the same field of endoluminal stents, a method of making a stent by using vacuum deposition techniques (col.3 line 52-col.4 line 30) as an improvement over older techniques such as cutting and etching etc. (col.1, lines 31-51; cutting being the only type mentioned by Brown), in order to improve the properties of the material (discloses control of microstructure, col.2, lines 6-9; col.3, lines 18-25; also as Whicher discloses the same method of manufacture, vacuum deposition, Whicher process will inherently produce microstructure and heterogeneities, since such control over properties are characteristic of such a process). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Brown's endoluminal stent shape, with Whicher's method of manufacture (vacuum deposition) in order to provide a stent with improved material properties.

Referring to dependent claims, Brown discloses a degradable plug (biodegradable matrix 27; shown in the cavities and extending into the pores, see fig.3, 9 for example; col.8 line 62-col.9 line 5), the metals claimed (col.7, lines 12-18), bioactive agents claimed (col.5, lines 1-27), and a plurality of independent cavities (each structural element 12 in the mesh stent may have its own cavity, thus plurality of cavities amongst all the structural elements 12; further, elements 12 are shown to have multiple cavities fig.9 for example; further, at least one cavity is disclosed, encompassing more than one, col.2, lines 59-61). The claimed controlled heterogeneities (claims

30-37) are inherent to the deposition process taught by Whicher (As Whicher discloses the same process used with the same materials as the applicant such heterogeneities are inherently controlled just as much as they are "controlled" by the applicant since applicant has disclosed in the specification that the control of heterogeneities are a result of the vacuum deposition process; Whicher further discloses controlling the microstructure, see col.2, lines 15-32; col.3, lines 15-25; and Board Decision of related application 09/707,685 mailed September 30, 2008).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738